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|--|------------|--|--|
| 用机   |            | Application Number                     | 10/773,083   |
| <b>TRANSMITTAL</b>                                       |            | Filing Date                            | 02/04/2004   |
| FORM   |            | First Named Inventor                   | Daniel J. CUA  |
|  | PIS \      | Art Unit                               | 1615   |
| (to be used for all correspondence after initial filing) |            | Examiner Name                          |  |
| Total Number of Pages in This Submission                 | 9          | Attorney Docket Number                 | DX06023 US 01  |

|              |  | ENCLOSURES (Check all that ap                    | ply)  |  |  |  |  |  |
|--------------|--|--|---|--|--|--|--|--|
|              | Fee Transmittal Form                                 | Drawing(s)                                       | After Allowance Communication to Group                            |  |  |  |  |  |
|              | Fee Attached   | Licensing-related Papers                         | Appeal Communication to Board                                     |  |  |  |  |  |
| _            | Amendment/Reply                                      | Petition   | of Appeals and Interferences                                      |  |  |  |  |  |
|              | After Final  | Petition to Convert to a Provisional Application | Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) |  |  |  |  |  |
|              | Affidavits/declaration(s)                            | Power of Attorney, Revocation                    | Proprietary Information   |  |  |  |  |  |
|              | Extension of Time Request                            | Change of Correspondence Address                 | Status Letter   |  |  |  |  |  |
|              | Express Abandonment Request                          | Terminal Disclaimer                              | V Other Frederica (a) (alarge                                     |  |  |  |  |  |
| <u>X</u>     | Information Disclosure Statemen                      | Request for Refund                               | X Other Enclosure(s) (please Identify below):                     |  |  |  |  |  |
|              | (2 pages)  | CD, Number of CD(s)                              |   |  |  |  |  |  |
| _            | Certified Copy of Priority Document(s)               | Other Enclosures/Remarks:                        |   |  |  |  |  |  |
|              |  | Form PTO/SB/08 (6 pages)                         |   |  |  |  |  |  |
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|              | under 37 CFR 1.52.or 1.5                             |  |   |  |  |  |  |  |
|              |  | SIGNATURE OF APPLICANT, ATTORNEY, OF             | RAGENT  |  |  |  |  |  |
| Firm         | Sheela Mohan-P<br>DNAX Research,                     | terson, Reg. No. 41,201<br>Inc.                  |   |  |  |  |  |  |
| or<br>Indivi | dual 901 California Av<br>Palo Alto, CA 94           |  |   |  |  |  |  |  |
| Signa        | ature Sheek Sok                                      | Ph   |   |  |  |  |  |  |
| Date         | Sheele tok<br>28 - July -                            | 2004   |   |  |  |  |  |  |
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Attorney Docket: DX06023US01

IN THE UNITED S

NT AND TRADEMARK OFFICE

Examiner: Unknown

Art Unit: 1615

Conf. No.: 3286

Re application of:

Daniel J. CUA, et al.

Application No.: 10/773,083

Filed: 02/04/2004

For: USES OF MAMMALIAN

CYTOKINE; RELATED

**REAGENTS** 

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## INFORMATION DISCLOSURE STATEMENT

Sir:

The materials as listed in the attached form PTO/SB/08 are brought to the Examiner's attention pursuant to the duty of disclosure under 37 C.F.R. § 1.56, § 1.97, and § 1.98.

Citation of these documents should not be construed as a representation that the documents are in fact material or are in fact prior art with respect to the instant invention. The Examiner should not make any inference relating to the relative pertinence of cited references based upon the order in which the art is presented. Citation of these documents should not be construed as a representation that a search has been made or that more pertinent art may not be in existence.

Applicants request that the Examiner fully consider the art cited in the attached PTO/SB/08 form. Applicants further request that the Patent and Trademark Office list all such art on the front of any patent issuing from this application.

Applicants believe no fee is required for filing this document; however, if such a fee is required, the Commissioner is hereby authorized to charge DNAX Research Institute Deposit account no. 04-1239.

Respectfully submitted,

Date: 28- July-20

Sheela Mohan-Peterson, Reg. No.

41,201

Attorney for Applicants

Customer No. 28008 DNAX Research, Inc. 901 California Avenue Palo Alto, CA 94304-1104

Telephone (Switchboard): (650) 496-6400 Telephone No. (Direct): (650) 496-1244

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|---|---------------------------------|---------------|------------------------|-------------------|
| ١ |                                 | 1001 001105   | Application Number     | 10/773,083        |
|   | INFORMATION D                   | ADDITIONALE   | Filing Date            | 02/04/2004        |
| X | O STATEMENT BY                  | APPLICANT     | First Named Inventor   | Daniel J. CUA     |
|   | JUL 3, 0, 2004 as many sheets a | as necessary) | Art Unit               | 1615              |
|   | JUL 3, U, ZULA                  |               | Examiner Name          |                   |
| Ì | Sheet 1 of                      | 6             | Attorney Docket Number | DX06023US01       |

|                       |              |   | U.S. PATEN                     | IT DOCUMENTS                                       |  |
|-----------------------|--------------|---|--------------------------------|--|--|
| Examiner<br>Initials* | Cite<br>No.1 | DOCUMENT NUMBER  Number-Kind Code <sup>2 (if known)</sup> | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant, Passages or Relevant<br>Figures Appear |
|                       |              |   |                                |  |  |

| -                     | FOREIGN PATENT DOCUMENTS |   |                                |  |  |   |
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| Examiner<br>Initials* | Cite<br>No.1             | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant, Passages or Relevant |   |
| muais                 | 110.                     | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5 (il known)</sup> | MIVEDD-1111                    | Applicant of Cited Document                        | Figures Appear   | Ŀ |
|                       |                          |   |                                |  |  |   |

|                       |              | NON PATENT LITERATURE DOCUMENTS   | ·              |
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|                       | AA           | Andoh, et al. (2002) Int. J. Mol. Med. 10:631-634<br>"Interleukin (IL)-4 and IL-17 Synergistically Stimulate IL-6 Secretion in Human Colonic Myofibroblasts"  |                |
|                       | AB           | Annacker, et al. (2001) J. Immunol. 166:3008-3018 "CD25 <sup>+</sup> CD4 <sup>+</sup> T Cells Regulate the Expansion of Peripheral CD4 T Cells Through the Production of IL-10 <sup>1</sup> "   |                |
|                       | AC           | Atreya, et al. (2000) Nature Med. 6:583-588  "Blockade of interleukin 6 trans signaling suppresses T-cell resistance against apoptosis in chronic intestinal inflammation: Evidence in Crohn disease and experimental colitis in vivo"                          |                |
|                       | AD           | Berg, et al. (1996) J. Clin. Invest. 98:1010-1012<br>"Enterocolitis and Colon Cancer in Interleukin-10-deficient Mice Are Associated with Aberrant Cytokine Production and CD4 <sup>+</sup> TH1-like Responses"   |                |
|                       | AE           | Bhan, et al. (1999) Immunol. Rev. 169:195-207 "Colitis in transgenic and knockout animals as models of human inflammatory bowel disease"  |                |

| Examiner<br>Signature | Date<br>Considered |  |
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|       |   |        |              | Application Number     | 10/773,083        |
|       | • |        | SCLOSURE     | Filing Date            | 02/04/2004        |
| SI    | AIEMENI                                 | 3 Y A  | APPLICANT    | First Named Inventor   | Daniel J. CUA     |
|       | (Use as many sh                         | eets a | s necessary) | Art Unit               | 1615              |
|       |   |        |              | Examiner Name          |                   |
| Sheet | 2                                       | of     | 6            | Attorney Docket Number | DX06023US01       |

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| Examiner Initials* | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                    | AF           | Boddeke (2001) Euro. J. Pharmacol. 429:115-119 "Involvement of chemokines in pain"  |                |
| •                  | AG           | Bouma and Strober (2003) Nat. Rev. Immunol. 3:521-533 "The Immunological and Genetic Basis of Inflammatory Bowel Disease"   |                |
|                    | АН           | Calcutt (2002) Int. Rev. Neurobiol. 50:205-228 "Potential Mechanisms of Neuropathic Pain in Diabetes"   |                |
|                    | AI           | Chu, et al. (2000) J. Exp. Med. 192:123-128  "Failure to Suppress the Expansion of the Activated CD4 T Cell Population in Interferon y-deficient Mice Leads to Exacerbation of Experimental Autoimmune Encephalomyelitis"                                       |                |
|                    | AJ           | Cua, et al. (2003) Nature 421:744-748 "Interleukin-23 rather than interleukin-12 is the critical cytokine for autoimmune inflammation of the brain"   |                |
|                    | AK           | Davidson, et al. (1998) J. Immunol. 161:3143-3149<br>"IL-12, But Not IFN-γ, Plays a Major Role in Sustaining the Chronic Phase of Colitis in IL-10-Deficient Mice"  |                |
|                    | AL           | Davidson, et al. (1996) J. Exp. Med. 184:241-251<br>"T Helper Cell 1-type CD4 <sup>+</sup> T Cells, but Not B Cells, Mediate Colitis in Interleukin 10-deficient Mice"  |                |
|                    | AM           | Elkins, et al. (2002) Infection Immunity 70:1936-1948 "In Vivo Clearance of an Intracellular Bacterium, Francisella tularensis LVS, Is Dependent on the p40 Subunit of Interleukin-12 (IL-12) but Not on IL-12 p70"   |                |
|                    | AN           | Fossiez (1998) Int. Rev. Immunol. 16:541-551 "Interleukin-17"   |                |
| •                  | AO           | Frucht (2002) Sci STKE 2002, E1-E3 "IL-23: A Cytokine That Acts on Memory T Cells"  |                |
|                    | AP           | Fujino, et al. (2003) Gut 52:65-70 "Increased expression of interleukin 17 in inflammatory bowel disease"   |                |

| Examiner<br>Signature | Date<br>Considered |  |
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|       |   |        |              | Application Number     | 10/773,083        |
|       | • |        | SCLOSURE     | Filing Date            | 02/04/2004        |
| 51    | AIEWENI                                 | BY     | APPLICANT    | First Named Inventor   | Daniel J. CUA     |
|       | (Use as many sh                         | eets a | s necessary) | Art Unit               | 1615              |
|       |   |        |              | Examiner Name          |                   |
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|                    |              | NON PATENT LITERATURE DOCUMENTS   |                |
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|                    | AQ           | Green (2003) The Lancet 362:383-391 "Coeliac disease"   |                |
|                    | AR           | Griffin and Mrak (2002) <i>J. Leukocyte Biol.</i> 72:233-238 "Interleukin-1 in the genesis and progression of and risk for development of neuronal degeneration in Alzheimer's disease"   |                |
|                    | AS           | Gross, et al. (1992) Gastroenterol. 102:514-519 "Evidence for Continuous Stimulation of Interleukin-6 Production in Crohn's Disease"  |                |
|                    | AT           | Hanauer (1996) New Engl. J. Med. 334:841-848 "Inflammatory Bowel Disease"   |                |
|                    | AU           | Hata, et al. (2002) Am. J. Physiol. Gastrointest. Liver Physiol. 282:G1035-G1044 "IL-17 stimulates inflammatory responses via NF-kB and MAP kinase pathways in human colonic myofibroblasts"  |                |
|                    | AV           | Hickey, et al. (1991) J. Neurosci. Res. 28, 254-60<br>"T-Lymphocyte Entry Into the Central Nervous System"  |                |
|                    | AW           | Hoozemans, et al. (2001) Exp. Gerontol. 36:559-570<br>"Interleukin-1β induced cyclooxygenase 2 expression and prostaglandin E2 secretion by human neuroblastoma cells: implications for Alzheimer's disease"  |                |
|                    | AX           | Horwitz and Fisher (2001) New Engl. J. Med. 344:1846-1850<br>"The Irritable Bowel Syndrome"   |                |
|                    | AY.          | Hurst, et al. (2002) J. Immunol. 169:443-453 "New IL-17 Family Members Promote Th1 or Th2 Responses in the Lung: In Vivo Function of the Novel Cytokine IL-25"  |                |
|                    | AZ           | Ilzecka, et al. (2002) Cytokine 20:239-243<br>'Transforming Growth Factor-Beta 1 (TGF-BETA 1) in Patients with Amyotrophic Lateral Sclerosis"   |                |
|                    | ВА           | Ito, et al. (2002) J Gastroenterol. 37 Suppl. 14:56-61.<br>"Anti-IL-6 receptor monoclonal antibody inhibits leukocyte recruitment and promotes T-cell apoptosis in a murine model of Crohn's disease"   |                |

| Examiner<br>Signature | Date<br>Considered |  |
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|                        |   |                        |              | Application Number   | 10/773,083    |  |
| • • • • • •            | • |                        | SCLOSURE     | Filing Date          | 02/04/2004    |  |
| STATEMENT BY APPLICANT |   |                        |              | First Named Inventor | Daniel J. CUA |  |
|                        | (Use as many sh                         | eets a                 | s necessary) | Art Unit             | 1615          |  |
|                        |   |                        |              | Examiner Name        |               |  |
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|                    | ВВ           | Kostulas, et al. (1999) Stroke 30:2174-2179  "Increased IL-1β, IL-8, and IL-17 mRNA Expression in Blood Mononuclear Cells Observed in a Prospective Ischemic Stroke Study"  |                |
|                    | вс           | Levy (1996) New Engl. J. Med. 335:1124-1132 "Pharmacologic Treatment of Cancer Pain"  |                |
|                    | BD           | Li, et al. (2001) J. Neuroimmunol. 116:5-14<br>"IL-17 and IFN-γ mRNA expression is increased in the brain and systemically after permanent middle cerebral artery occlusion in the rat"   |                |
|                    | BE           | Lindenlaub and Sommer (2003) Acta Neuropathol. (Berl.) 105:593-602<br>"Cytokines in sural nerve biopsies from inflammatory and non-inflammatory neuropathies"   |                |
|                    | BF           | Lock, et al. (2002) Nature Med. 8:500-508 "Gene-microarray analysis of multiple sclerosis lesions yields new targets validated in autoimmune encephalomyelitis"   |                |
|                    | BG           | Matthys, et al. (2000) J. Leukocyte Biology 68:447-454<br>"The protective effect of IFN-y in experimental autoimmune diseases: a central role of mycobacterial adjuvant-induced myelopoiesis"   |                |
| *****              | вн           | Matthys, et al. (2001) Trends Immunol. 22:367-371<br>"Mac-1+ myelopoiesis induced by CFA: a clue to the paradoxical effects of IFN-γ in autoimmune disease models"  |                |
|                    | ВІ           | Matusevicius, et al. (1999) Multiple Sclerosis 5:101-104<br>"Interleukin-17 mRNA expression in blood and CSF mononuclear cells is augmented in multiple sclerosis"  |                |
| · ·                | ВЈ           | McManus and Kelleher (2003) New Engl. J. Med. 348:2573-2574<br>"Celiac Disease – The Villain Unmasked?"   |                |
|                    | вк           | Neurath, et al. (1995) J. Exp. Med. 182:1281-1290 "Antibodies to Interleukin 12 Abrogate Established Experimental Colitis in Mice"  |                |

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|                    | BL           | Nielsen, et al. (2003) Scand. J. Gastroenterol. 38:180-185<br>"Upregulation of Interleukin-12 and -17 in Active Inflammatory Bowel Disease".  |                |
|                    | ВМ           | Oppmann, et al. (2000) Immunity 13:715-725 "Novel p19 Protein Engages IL-12p40 to Form a Cytokine, IL-23, with Biological Activities Similar as Well as Distinct from IL-12"  |                |
|                    | BN           | Parham, et al.(2002) J Immunol 168:5699-708  "A Receptor for the Heterodimeric Cytokine IL-23 Is Composed of IL-12Rβ1 and a Novel Cytokine Receptor Subunit, IL-23R"  |                |
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|                        |                         |        | COL OCUPE                          | Application Number   | 10/773,083    |  |
|                        |                         |        | SCLOSURE                           | Filing Date          | 02/04/2004    |  |
| STATEMENT BY APPLICANT |                         |        |                                    | First Named Inventor | Daniel J. CUA |  |
|                        | (Use as many sh         | eets a | s necessary)                       | Art Unit             | 1615          |  |
|                        |                         |        |                                    | Examiner Name        |               |  |
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|                    |              | NON PATENT LITERATURE DOCUMENTS   |                |
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